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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,872	CALLEN ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *74,108,112-116 and 118-121* is/are withdrawn from consideration.

5)☒ Claim(s) *3* is/are allowed.

6)☒ Claim(s) *1, 2, 4, 6-12, 16-17, 47, 48, 75-80, 84-86, 88, 89, 92, 93, 102-107,and 122-124* is/are rejected.

7)☒ Claim(s) *14 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-12,14-17,47,48,74-80,84-86,88,89,92,93,102-108,112-116 and 118-124.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/20/04 has been entered.

Claims 5, 13, 18-46, 49-73, 81-83, 87, 90-91, 94-101, 109-111, and 117 have been canceled. Claims 1-4, 6-12, 14-17, 47, 48, 74-80, 84-86, 88, 89, 92, 93, 102-108, 112-116, 118-121 and newly presented claims 122-124 are still at issue and are present for examination.

Applicants' arguments filed on 8/20/04, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 74, 108, 112-116 and 118-121 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the

restriction requirement in the response filed 6/23/03. Claims 1-4, 6-12, 14-17, 47, 48, 75-80, 84-86, 88, 89, 92, 93, 102-107, and newly presented claims 122-124 are examined herein.

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As amended Claim 1 requires that the sequence identity be present over the entire sequence. As such the scope of these claims is identical.

Claim 124 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As amended Claim 47 requires that the sequence identity be present over the entire sequence. As such the scope of these claims is identical.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-9 are confusing in the recitation of "has at least 90% (or 95% or 97%) sequence identity over a region of … consecutive residues" as it does not identify to what sequence the identity must be found. For purposes of examination it is presumed that it was intended to read "has at least 90% (or 95% or 97%) sequence identity to SEQ ID NO:125 over a region of … consecutive residues"

Claims 10-12, 17, 48, 75-80, 84-86, 88, 89, 92, 93, and 102-107 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 is directed to polynucleotides encoding an alpha amylase and having at least 95% sequence identity to 75 nucleotides of SEQ ID NO:125 or a complement thereof. Claim 11 is directed to polynucleotides encoding an alpha amylase and having at least 97% sequence identity to 50 nucleotides of SEQ ID NO:125 or a complement thereof. Claim 12 is directed to

polynucleotides encoding an alpha amylase and having at least 90% sequence identity to 200 nucleotides of SEQ ID NO:125 or a complement thereof. Claims 75-80, 84-86 88-89, and 92 are drawn to polynucleotides which hybridizes to the polynucleotide of Claim 10 under low or high stringency conditions. Claims 17 and 93 recite polynucleotides comprising fragments of SEQ ID NO:125 and Claims 48 and 102-107 recite vectors and host cells comprising the nucleic acids of claims 10 or 12 or methods of expressing said nucleic acids. Claims 10-12, 17, 48, 75-80, 84-86, 88, 89, 92, 93, and 102-107 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polynucleotides and variants and fragments thereof that have not been disclosed in the specification. No description has been provided of the structure and function of the modified polynucleotide sequences encompassed by the claims. No information, beyond the characterization of SEQ ID NO:125 which encodes the amylase of SEQ ID NO:126 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polynucleotides. The specification does not contain any disclosure of the structure and function of all the polynucleotide sequences derived from SEQ ID NO:125, including fragments and variants within the scope of the claimed

genera. The genera of polynucleotides claimed is a large variable genus including polynucleotides which can have a wide variety of structures and functions. It should be noted that even within Claims 10-12, 48, and 102-107 which are limited to polynucleotides encoding polypeptides with amylase activity there are a wide variety of structures encompassed as the structural limitations recited require similarity to only 50-200 nucleotides of a 1395 residue sequence. Therefore many structurally unrelated polynucleotides are encompassed within the scope of these claims. The specification discloses only a small number of species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Applicants submit that the claimed invention is sufficiently described in the specification so that one of

ordinary skill in the art would be able to ascertain the scope of the claims with reasonable clarity and recognize that applicants were in possession of the claimed invention. In support of applicants position applicants again refer to the USPTO guidelines concerning compliance with the written description requirement of U.S.C. 112 first paragraph, specifically example 14. Applicants argument is not found persuasive for the following reasons. First it should be pointed out that the most of the rejected claims have no functional limitations at all. None of Claims 17, 75-80, 84-86, 88, 89, 92, or 93 require the claimed nucleic acids to encode an alpha amylase or have any other functional limitation present. As such applicants analogy to example 14 for these claims is totally inconsistent. The remaining rejected claims i.e., 10-12, 48 and 102-107 do require the claimed nucleic acids to encode an alpha amylase and thus do have a both a structural and functional limitation as found in Example 14 of the guidelines. Applicants argue that "The sequences encompassed by the present claims are described via shared physical and structural properties in terms that convey with reasonable clarity to those skilled in the art that Applicants, as of the filing date and at the time of the invention, were in possession of the claimed

invention". However, these claims lack sufficient structural limitations to adequately describe the genus. The requirements for written description of a genus of nucleic acids as set forth in University of California v. Eli Lilly & Co., 43 USPQ2d 1398 (Fed. Cir. 1997) may be achieved by a recitation of a representative number of DNAs defined by nucleotide sequence or a recitation of structural features common to members of the genus, which features **constitute a substantial potion of the genus**. Claims 10-12, 48 and 102-107 all recite nucleic acids which comprise only 50-200 residues having 90-97% identity to a portion of SEQ ID NO:125 as the only recited structural limitations of the claims. These recited structural features of the genus do not constitute a substantial potion of the genus as the remainder of the structure of a nucleic acid encoding a polypeptide with alpha amylase activity is completely undefined. Fragments consisting of only 50-200 residues having 90-97% identity to a portion of SEQ ID NO:125 are highly unlikely to have alpha amylase activity, constitute only a very small portion of the structure of the only disclosed species (SEQ ID NO:125) and the specification does not define the remaining structural features necessary for members of the genus to be selected. As such the shared structural features of the

claimed genera are clearly insufficient to put the skilled artisan in possession of the entire genus.

Applicants further argue that Claim 92 is analogous to Example 9 of the Written description Guidelines. However, Claim 92 (as well as the other probe claims i.e., Claims 17, 75-80, 84-86, 88-89, and 93) is not analogous to the claim of example 9. The claim recited in example 9 is limited to a genus of nucleic acids which all have the same function (i.e., encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity) while applicants claims are not as has been repeatedly noted in previous Office Actions. Significantly the claim of example 9 does not read "An isolated nucleic acid (or An oligonucleotide probe) that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1." nor do applicants claims read "An oligonucleotide probe that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO:125 wherein said oligonucleotide probe encodes a protein having alpha amylase activity." Applicants state that Example 9 is silent with regard to the number and percentage of sequences that did not encode proteins having activity similar to SEQ ID NO:1. While

this is true, in Example 9, **these sequences are not claimed** while in the instant situation applicants claims encompass such sequences. Applicants argue that the Guidelines indicate that importation of specific hybridization conditions into the claim text is not required to meet the written description requirements. However, applicants have never been required to import specific hybridization conditions into the claim text to meet the written description requirements. In the instant application importation of specific hybridization conditions into the claims was necessary to meet the definiteness requirements of 112, 2nd paragraph and **not** in order to meet the written description requirement. For all the above reasons applicants claims are not analogous to those of Example 9 of the guidelines, and lack sufficient written description for all the reasons previously discussed.

Claims 1, 2, 4, 6-12, 16, 17, 47, 48, 75-80, 84-86, 88, 89, 92, 93, 102-107, and 122-124 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding SEQ ID NO:126, does not reasonably provide enablement for any polynucleotide having at least 85% sequence identity to SEQ ID NO:125 and encoding a polypeptide with an alpha amylase activity or any polynucleotide comprising

at least 50-200 bases of a sequence having 90-97% identity to SEQ ID NO:125, or any polynucleotide comprising a fragment of SEQ ID NO:125, or all fragments and variants thereof or vectors and host cells comprising said nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1, 2, 4, 6-12, 16, 17, 47, 48, 75-80, 84-86, 88, 89, 92, 93, 102-107, and 122-124 are directed to polynucleotides having at least 85% sequence identity to SEQ ID NO:125 and encoding a polypeptide with an alpha amylase activity or any polynucleotide comprising at least 50-200 bases of a sequence having 90-97% identity to SEQ ID NO:125, or any polynucleotide comprising a fragment of SEQ ID NO:125, or all fragments and variants thereof or vectors and host cells comprising said nucleic acids or methods of expressing said nucleic acids. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides encoding amylases and variants and fragments thereof broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be

tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the polynucleotide of SEQ ID NO:125 which encodes the alpha amylase of SEQ ID NOS 126.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass an enormous number of polynucleotide

fragments and variants of the polynucleotide of SEQ ID NO:125 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting amylase activity; (B) the general tolerance of amylases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including an enormous number of polynucleotide fragments and variants of the polynucleotide of SEQ ID NO:125. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and

undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicants argue that the specification enabled the invention as claimed. Applicants refer to declarations by inventor Jay Short, who declares that the state of the art at the time of the invention and the level of skill of the person of ordinary skill in the art was very high. Dr Short's declarations further states that one of skill in the art at the time of the invention could use the teachings of the specification and other protocols known in the art to screen for nucleic acids encoding polypeptides having alpha amylase activity and that while the number of samples needed to be screened may have been high, the screening procedures were routine and successful results predictable. According to Dr. Short's declaration, knowledge of the specific structural elements which correlate with alpha amylase activity would not have been required to create variants and test them for activity. Applicants further argue that enablement is not precluded by the necessity to screen large number of compositions as long as that screening is routine. Applicants refer to *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* as support for the argument that the claimed invention is enabled

even if there is a need to screen large numbers of negatives to find a sample with the desired activity.

As indicated in the previous Office Action, the specification is completely silent in regard to which are the amino acid residues which can be substituted, deleted, or inserted in the nucleic acid of SEQ ID NO:125 to obtain structural homologs of the nucleic acid of SEQ ID NO:125 as recited in the claims which encode proteins with alpha amylase activity. In addition, the specification does not provide any clue as to which 50-200 consecutive base fragments of the nucleic acid of SEQ ID NO:125 are required to encode proteins with alpha amylase activity nor does it provide any clue as to which fragments of a nucleic acid having at least 90-97% sequence identity to the SEQ ID NO:125 and encoding an alpha amylase are essential for alpha amylase activity. The prior art clearly teaches the unpredictability of assigning function based on structural homology and how small structural changes can lead to major changes in function. (See Bork, Broun et al., Van de Loo et al., Witkowski et al. and Seffernick et al. as discussed in the previous action). Furthermore, it should be noted that applicants claims encompass not only nucleic acids having minor changes in structure from SEQ ID NO:125, but include nucleic

acids with major changes as well. Therefore, in the absence of any information as to how structure correlates with function, one of skill in the art would have to go through the burden of undue experimentation to isolate/make the nucleic acids as encompassed by the claims, to practice the full scope of the claimed invention.

The declarations of Dr Short state that methods of making variants of a known sequence are well known in the art, including methods which result in more than one change in a sequence and that the skilled artisan is capable of screening any specific sequence to determine if it has activity. This is not disputed by the examiner. However, applicants arguments amount to a conclusion that screening for a needle in a haystack should be enabled because the artisan knows how to look for it, can identify it when it is seen and knows it is there somewhere. This is not case. It is well established that while enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the **specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.** The only guidance present in the specification for selecting the needle in the haystack (i.e., any polynucleotide having at least 85%

sequence identity to SEQ ID NO:125 and encoding a polypeptide with an alpha amylase activity or any polynucleotide comprising at least 50-200 bases of a sequence having 90-97% identity to SEQ ID NO:125, or any polynucleotide comprising a fragment of SEQ ID NO:125) is the sequence of SEQ ID NOS:125 itself. This is clearly insufficient given that the claims require little structural homology to these sequences to be maintained (i.e., the haystack is enormous) and the known fact that only a very minuscule portion of the sequences having claimed structural features will have alpha amylase activity (i.e., the needle is very tiny). Applicants argue that the specification does provide guidance for what changes can be made by teaching on pages 17 to 18 of the specification that a "substantially identical' amino acid sequence is a sequence that differs from a reference sequence by one or more conservative or non-conservative amino acid substitutions, deletions, or insertions, particularly when such a substitution occurs at a site that is not the active site of the molecule, and provided that the polypeptide essentially retains its functional properties" and that direction to the skilled artisan as to which amino acid residues can be substituted, deleted or inserted into a nucleic acid to obtain structural, and functional, homologues could also

be found in the art at the time of the invention as the three dimensional structure of amylases had been described, thus providing direction as to which amino acid residues can be modified and how structure correlates with function and that at the time of the invention one of skill in the art would have been aware of the many studies of amylase activity and active sites. The disclosure of pages 17 and 18 merely discusses which amino acids substitutions could be considered "conservative" and suggests making substitutions outside of the active site. This guidance is generic in nature and in no way specific to the nucleic acid of SEQ ID NO:125 such that it provides guidance for the modification of this nucleic acid. While it is true as applicants discuss that the art with regard to alpha amylases does provide a substantial amount of guidance including three dimensional structures of several enzymes as well as substantial amounts of mutagenesis, it should be noted that all of the alpha amylases for which such information is available differ substantially in structure from the alpha amylase encoded by SEQ ID NO:125. Furthermore, it should be noted that applicants have not been limited to only the nucleic acid of SEQ ID NO:125. Claims which include many variants of this nucleic acid but which limit the total number of changes to a scope that is

within the level of skill of the ordinary artisan given the guidance provided in the specification and the art (i.e., Claims 3, 14, and 15) have not been rejected.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4, 7-12, 17, 47, 48, 75-80, 84-86, 92, 102-107, and 123-124 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana et al. (Reference AK of applicant's IDS).

Tachibana et al. teach the isolation and expression of a polynucleotide encoding *Pyrococcus* sp. KOD1 alpha amylase. This polynucleotide has 80% identity to SEQ ID NO:125 and encodes a protein with 85% identity to SEQ ID NO:126. Therefore Tachibana et al. anticipate Claims 47 and 124. Furthermore, while the entire gene of Tachibana et al. does not have 85% identity to the entire sequence of SEQ ID NO:125, it clearly would hybridize to such a sequence under high stringency conditions (as it has at least 95% identity to many polynucleotides having 85% identity to SEQ ID NO:125) and thus anticipates claims 2, 4 and

17. The gene of Tachibana et al. also comprises a sequence of at lest 200 nucleotides having 90% identity to SEQ ID NO:125 (i.e., residues 1112-1314 of Tachibana et al. have 90% identity to residues 667-869 of SEQ ID NO:125) and thus anticipates claims 7, 12 and 48, a region of 75 nucleotides having greater than 95% identity (i.e., residues 1463-1537 of Tachibana et al. have 95% identity to residues 1018-1092 of SEQ ID NO:125) and thus anticipate claims 8, 10, 48, 75-80, 84-86, 92 and 102-107 and comprises a region of 50 nucleotides having greater than 97% identity (i.e., residues 1469-1530 of Tachibana et al. have 97% identity to residues 1024-1085 of SEQ ID NO:125) and thus anticipate claims 9 and 11. The protein encoded by the gene of Tachibana et al. comprises a region of 100 amino acids having greater than 98% identity (i.e., residues 264-367 of Tachibana et al. have 98% identity to residues 266-369 of SEQ ID NO:126). And therefore it anticipates claim 123.

Applicants appear to believe that the amendments to the claims overcame the above rejection. However, as explained above, the gene to Tachibana et al. meets all limitations of each of the rejected claims and thus the rejection is maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana et al. (Reference AK).

Tachibana et al. is discussed above. The nucleic acid of Tachibana et al. differs from those of the instant claims only in that the nucleic acids of the claims include a detectable label.

As the identification of other amylase genes would be desirable, it would have been obvious to one of ordinary skill in the art to label the nucleic acid of Tachibana et al. in order to use this nucleic acid as a probe for related amylase genes of other organisms. Use of any of the many well known

types of labeling compounds (radioisotopes, fluorescent compounds, chemiluminescent compounds, enzymes such as horse radish peroxidase or alkaline phosphatase, etc. or haptens) would have been obvious to one of skill in the art.

Applicant has not presented any arguments specifically traversing this rejection but instead relies upon the traversal discussed above. Therefore, this rejection is maintained for the reasons presented above.

Claim 3 is allowed. The gene of Tachibana et al. is not sufficiently similar to the gene of SEQ ID NO:125 to hybridize thereto under the high stringency conditions of the instant claim nor doe the art suggest modifications of the prior art gene which would result in a gene within the scope of Claim 3.

Claims 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura

Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Rebecca Prouty
Primary Examiner
Art Unit 1652